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EXAMINER	
EPPERSON, JON D	
ART UNIT	PAPER NUMBER
1639	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
File Copy	09/738,871	SHORT ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *1-64 and 72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). 9 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on May 12, 2003 (Paper No. 7).

Status of the Claims

2. Claims 1-72 are pending in the present application.

3. Applicants' response to the Restriction and/or Election of Species requirements in Paper No. 7 is acknowledged (Applicants elected Group III, claims 65-72) and claims 1-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim (see below i.e., ***Response to Restriction and/or Election of Species***).

4. Please note: Applicant's elected species (subgroup 1 = thermophiles, subgroup 2 = gel microdroplets, subgroup 3 = flow cytometer and superconducting interference device) were found in the art, see rejections below. Applicant is reminded of MPEP § 803.02 with respect to species elections:

> On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-

type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

5. Claim 72 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species, the requirement having been traversed in Paper No. 7 (see below i.e., ***Response to Restriction and/or Election of Species***).

6. Therefore, claims 65-71 are examined on the merits in this action.

Priority Claims

7. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is a CIP of 09/685432, which is a CIP of 09/444112, which is a CIP of 09/098,206, which is a CIP of 08/876,276 to which priority under 35 U.S.C. 120 is claimed. However, the applications upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the claims of this application. In the instant case, none of the applications disclose magnetic field sensing devices like Superconducting Quantum Interference Device i.e., SQUID or multipole coupling device (e.g., see claims 70-71). If applicant believes this to be in error, applicant must disclose where in the specification support for SQUID can be found (i.e., indicate, page, paragraph and line numbers). Therefore the filing date of the instant application for claims 70-71 is deemed to be its actual filing date of **December 14, 2000**.

Response to Restriction and/or Election of Species

8. Applicant's election of Group III (claims 65-72) in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

9. Applicant's election of species in Paper No. 7 (subgroup 1 = thermophile; subgroup 2 = gel microdroplet; see also attached interview summary wherein Applicants elected both flow cytometer and SQUID for subgroup 3) with traverse is also acknowledged.

10. The election of species traversal is on the ground(s) that **[1]** "Applicants' invention is based on screening mixed populations of organisms in a microenvironment, for example a microdroplet, rather than the device that is utilized for the screening. Any type of flow cytometry device would be useful in the claimed invention and would not require a separate search" (see Paper No. 7, page 1), **[2]** "all of the methods for high throughput screening of a library of polynucleotides will have to be searched multiple times. Thus, the Examiner will be required to search the same group of references over and over again, causing much waste of time and energy" (see Paper No 7, page 2), **[3]** "Applicants will be required to file and prosecute multiple applications, entailing much delay and cost that could be avoided by rejoining the species in the claims" (see Paper No 7, page 2) and **[4]** "Applicant's invention is based on screening polynucleotides that encode an activity of interest, rather than the device that is utilized for the

screening or the fluorescent molecule or reporter system that is used. Any type of flow cytometry device or fluorescent molecule would be useful in the claimed invention and would not require a separate search" (see Paper No. 7, page 2).

11. These arguments were fully considered but were not found persuasive. The Examiner's position is that **[2]** there is no basis for the assertion that all of the methods would have to be searched "multiple times" and even if *assuming arguendo* that the methods did have to be searched "multiple times" this assertion is not relevant to the requirements of a species election (i.e., the Examiner only needs to show that the species are distinct and burdensome to search, see MPEP § 802-803). Furthermore, **[3]** there is also no basis for the assertion that Applicants would have to "file and prosecute multiple application, entailing much delay and cost" because it was already stated in Paper No. 4 that "Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141" (see Restriction Requirement, page 9, paragraph 14). Finally, **[1,4]** the Examiner has already stated that "[s]hould applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case" (see Restriction Requirement, page 8, paragraph 12). This has not been done.

12. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

13. The information disclosure statement filed May 16, 2003 (see Paper No. 8) fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because (1) the references have already been initialed by another person; (2) the 1449 forms contain the wrong serial number headings; (3) many of the references are repeated. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

14. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98 (b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on the form PTO-892, they have not been considered.

Specification

15. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 65-71 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 USC 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a written description rejection.

These claims encompass a broad genus. For example, claims 65-71 outline method steps for obtaining an organism from a mixed population of organisms by encapsulating at least one of said microorganisms in a microenvironment and separating said microorganism by flow cytometry. The specification and claims do not place any limit on the number of atoms, the types of atoms, or the manner in which said atoms might be connected to form the microenvironment. This reads on an infinite number of possibilities and thus represents

enormous scope. Furthermore, Applicants have not provided any common attributes that can link together ***all*** of these potential "microenvironments" i.e., there is no teaching that would allow a person of skill in the art to determine *a priori* ***all*** the different types of compounds that should be included in this enormous genus from the few examples provide by applicants. Furthermore, the specification only teaches "microorganisms" and, as a result, Applicants are not is possession of the broader organisms that are not microorganisms.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify ***all*** of the members of the genus or even a substantial portion thereof, and because the genus is enormous and highly variant, listing examples that are known in the art like gel microdroplets (e.g., Applicants' elected species, see also 35 U.S.C. § 102 rejections below) is insufficient to teach the entire genus. Consequently, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe this enormous genus. Thus, applicant was not in possession of the claimed genus.

With respect to adequate disclosure Applicant is referred to the discussion in *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175) regarding disclosure. For adequate disclosure, like enablement, requires *representative examples* which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that *applicant had possession of the full scope of the claimed invention.* See *In re Riat*_(CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr* (CCPA

1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and University *of California v. Eli Lilly and Co* cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure. Here, Applicants have not provided enough examples to show that they were in possession of the broad claims (see above).

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

17. Claims 65-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Powell et al (Powell, K. T.; Weaver, J. C. "Gel microdroplets and flow cytometry: rapid determination of antibody secretion by individual cells within a cell population" *Biotechnology* **April 1990**, 8, 4, 333-337).

For ***claim 65***, Powell et al discloses method steps for determining the secretion of biologically important macromolecules using gel microdroplets and flow cytometry (see Powell et al, entire document), which anticipates claim 1. For example, Powell et al discloses [a] encapsulating in a microenvironment at least one organism from the sample (see Powell et al, figure 1 showing "a process of capturing ... a single cell entrapped within a gel microdroplet"; see also page 334, column 2, paragraph 4 showing "preparations of agarose GMDs containing secreting cells (mouse hybridoma), non-producing cells (mouse masticytoma), or a mixed population of these cell"; see also figure 2), [b] incubating the encapsulated at least one organism under such conditions and for such a time to allow the at least one microorganism to grow or proliferate (see Powell et al, page 334, Incubation and fluorescence immunoassay section showing incubation on "aqueous culture medium capable of supporting cell metabolism and secretion" for incubation periods that are as "little as eleven hours ... (slightly less than one doubling time)" wherein the cells grow and secrete products), [c] sorting the encapsulated at least one organism by flow cytometry to obtain an organism from the sample (see Powell et al, abstract stating "the method combined flow cytometry with gel microdroplets"; see also figures 2-3; see also figure 1, "In a sorting flow cytometer, the GMD fluorescence signal could also be used as the basis of sorting").

For ***claims 66-67***, Powell et al states that a wide range of microorganisms can be used including *E. coli* and states that these can be from an environmental sample (see Powell et al, page 333, paragraph 1 stating "microorganisms were retained and accumulated within individual GMDs [i.e., Gel microdroplets]"; see also figure 1; see

also page 336, Discussion section, first paragraph stating "GMDs can be made from many types of gel material, to provide biocompatability for cells, so that many types of cells may be used"; see also reference 7 showing *E. coli* as an Example. Please note: *E. coli* can be found in environmental soil samples).

18. Claims 65-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Weaver et al (U.S. Patent No. 5,055,390) (Date of Patent is **October 8, 1991**).

For ***claim 65***, Weaver et al (see entire document) discloses a process for the chemical manipulation of liquid and gel microdroplets, which anticipates the claimed invention. For example Weaver et al discloses [a] encapsulating in a microenvironment at least one organism from the sample (see Weaver et al, see Summary of the Invention; see also column 41, lines 33-35, "Specimens of GMDs [i.e., gel microdroplets] which contain one or more microorganisms are ... grow[n]"; see also column 47, Measurements of Mixed Biological Populations section, especially column 47, lines 51-66), [b] incubating the encapsulated at least one organism under such conditions and for such a time to allow the at least one microorganism to grow or proliferate (see Weaver et al, column 31, Determination of Biological Growth section, see also column 41, lines 33-35, "Specimens of GMDs [i.e., gel microdroplets] which contain one or more microorganisms are ... grow[n]"; see also column 12, line 26; see also column 15, line 51; see also column 17, lines 25-35; see also column 17, lines 60-63, "Following an incubation, growth may occur and result in increases in size and number of cells, such

that an individually occupied microdroplet subsequently contains progeny cells of the initial single cell"), [c] sorting the encapsulated at least one organism by flow cytometry to obtain an organism from the sample (see Weaver et al, column 28, Capturing Molecules at Binding Sites in GMDs section; see also column 29, line 45, "sorting the GMDs by using a flow cytometer/cell sorter"; see also column 36, line 23).

For ***claims 66-67***, Weaver et al discloses a mixed population of microorganism from the environment (see Weaver et al, column 47, Measurements of Mixed Biological Populations section; see also column 1, line 19; see also column 2, line 18; see also column 42, Enumeration of Viable Biological Entities section; see especially, column 53, lines 34-66).

For ***claims 68-69***, Weaver et al discloses acid-producing microorganism e.g., acidophiles (see Weaver et al, column 5, lines 1-7, "allows detection of ... acid-producing microorganisms"; see also column 48, paragraph 2).

19. Claims 65-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Thompson et al (US Patent No. 5,824,485) (Filed **April 24, 1996**).

For ***claim 65***, Thompson et al (see entire document) discloses a method for screening molecular diversity using encapsulation techniques with an expression library derived form a plurality of species of organisms, which anticipates claim 1.

For example, Thompson et al discloses (a) encapsulating in a microenvironment at least one organisms from the sample (see Thompson et al, column 34, last paragraph;

see also column 35, paragraph 1; see section 5.2.3, especially column 37, lines 46 and 57 disclosing, for example, Applicant's elected gel microdroplet species). Thompson et al also discloses (b) incubating the said organisms for a sufficient time to allow them to grow and proliferate (e.g., see Thompson et al, column 39, line 29). Finally, Thompson et al discloses (c) sorting the encapsulated at least one organism by a flow cytometer to obtain an organism from the sample (see Thompson et al, column 33, line 39 e.g., disclosing the use of "FACS" sorting; see also column 37, line 35; see also column 35, paragraph 2, column 36, paragraph 2; see more generally section 5.2.2.; see also column 47, paragraph 1-7; see also column 49, paragraph 2).

For ***claim 66***, Thompson et al discloses an environmental sample (see Thompson et al, column 12, lines 38-44, "Any organism can be a donor organism for the purpose of preparing a combinatorial gene expression library of the invention ... from environmental samples either cultivable or uncultivable").

For ***claims 67-69***, Thompson et al discloses thermophiles, acidophiles, halphiles (see Thompson et al, column 14, paragraph 1).

For ***claim 70***, Thompson et al discloses fluorescence activated cell sorting (FACS), magnetic cell sorting (MACS), NMR (see Thompson et al, section 5.2.3, especially column 37, paragraph 3; see also column 47, line 50).

20. Claims 65-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al (US Patent No. 5,824,485) (Filed **April 24, 1996**) and Kotitz et al (Kotitz, R.; Bunte, T.; Weitschies, W.; Trahms, L. "Superconducting quantum interference device-based magnetic

nanoparticle relaxation measurement as a novel tool for the binding specific detection of biological binding reactions" *J. Appl. Phys.* **15 April 1997**, 81, 8, 4317).

For ***claims 65-70***, Thompson et al teaches all the limitations stated in the 35 U.S.C. 102(b) rejection above (incorporated in its entirety herein by reference), which anticipates claims 65-70 and, consequently, also renders obvious claims 65-70.

The prior art teaching of Thompson et al differs from the claimed invention as follows:

For ***claim 71***, the prior art teachings of Thompson et al differs from the claimed invention by not specifically reciting the use of a "Super Quantum Interference Device." Thompson et al is deficient in that it only teaches the use of fluorescence activated cell sorting (FACS), magnetic cell sorting (MACS), NMR (see Thompson et al, section 5.2.3, especially column 37, paragraph 3; see also column 47, line 50).

However, Kotitz et al teaches the following limitations that are deficient in Thompson et al:

For ***claim 71***, Kotitz et al (see entire document) teaches the use of a super quantum interference device (SQUID) (see Kotitz et al, abstract).

It would have been obvious to one skilled in the art at the time the invention was made to use SQUID as taught by Kotitz et al with the method of Thompson et al because Kotitz et al states that this technique is useful for detection of biological binding reactions and specifically points to antibody/antigen reactions (see title and abstract) that would include antibody/antigen reactions discussed by Thompson et al (see column 32, line 63; see also column 35, lin24). Furthermore, one of ordinary skill in the art would have been

motivated to use SQUID because Kotitz et al explicitly states that the technique shows a "higher sensitivity" for these systems (see Kotitz et al, abstract). Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because Kotitz et al shows a successful example with an analogous system.

Double Patenting

Statutory

21. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 USC 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

22. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

23. Claims 65-69 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 57-61 of copending Serial No. 09/685,432. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

24. Claims 65-69 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 of copending Serial No. 10/145,281 (US 20030077677 A1). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Non-statutory

25. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claims 65-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,174,673. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1986).

Although the conflicting claims are not identical, they are not patentably distinct from each other because, for example, claim 65 is generic to all that is recited in claim 1 of U.S. Patent No. 6,174,673 ('673). That is, claim 1 of '673 falls entirely within the scope of claim 65 of the present invention or, in other words, claim 65 is anticipated by claim 1 of '673. Specifically, the method of claim 1 in '673 is [a] a method for obtaining an organism for a mixed population of organisms in a sample via encapsulating in a microenvironment at least one organism from the sample (see '673, claim 1 (a) and (b) wherein the claim refers to a "clone" instead of the broader "organism"), [b] incubating the encapsulated at least one organism under such conditions and for such a time to allow the at least one microorganism to grow and proliferate (see '673, claim 1 (b) showing clones are "grown" long enough to express a bioactivity that allows for fluorescence detection), [c] sorting the encapsulated at least one organism by flow cytometry to obtain an organism from the sample (see '673, claim 1 (d) showing the use of a fluorescent analyzer, which is defined in the specification as i.e., the preferred embodiment is a fluorescence activated cell sorter).

Likewise claims 66-69 of the present application are generic to all that is recited in claim 9 of '673. That is claim 9 of '673 falls entirely within the scope of claims 66-69 or, on other word, claims 66-69 are anticipated by claim 9 of '673. Specifically the method of claim 9 in '673 recites microorganisms that are thermophiles, which anticipates claims 2-5 of the present application.

27. Claims 65-71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-21 of U.S. Patent No. 6,174,673 ('673) in view of Kotitz et al.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examiner application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1986).

Here, claim 1-21 of '673 (especially claims 1 and 9) recite the same method for obtaining an organism as that of the present invention (see above obviousness-type double patenting rejection, which is incorporated in its entirety herein by reference). The method of claims 70-72 differs from claims 1-21 of '673 by not reciting the use of a Super Conducting Quantum Interference Device. Kotitz et al discloses the use of a Super Conducting Quantum Interference Device for biological binding reactions that would encompass the binding reactions disclosed by '673 and thus render it obvious to combine the references (i.e., the references represent analogous art). Furthermore, a person of skill in the art would have been motivated to combine it to modify the method of claims 1-21 of '673 (especially claims 1, 9) to use a Super Conducting Quantum Interference Device as taught by Kotitz et al because Kotitz et al explicitly states that it a "higher sensitivity" can be obtained (see Kotitz et al, abstract).

Contact Information

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
August 4, 2003

BENNETT CELSA
PRIMARY EXAMINER